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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,581	11/09/2000	Ronald S. Vladyka JR.	FMC-1006US	2095

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,581

Applicant(s)

VLADYKA ET AL.

Examiner

EVERETT WHITE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed October 15, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claim 1 has been amended.
 - (E) Comments regarding Office Action have been provided drawn to
 - (a) 112, 2nd paragraph rejection, which has been withdrawn;
 - (b) 102(e) rejection, which has been maintained for the reasons of record;
 - (b) 103(a) rejection, which has been maintained for the reasons of record.
2. Claims 1-26 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. Claims 1, 2, and 4-11 stand rejected under 35 U.S.C. 102(e) as being anticipated by Asgharnejad et al (US Patent No. 6,123,964) for the reasons set forth on pages 3-5 of the Office Action mailed July 15, 2003.
5. Applicant's arguments filed October 15, 2003 have been fully considered but they are not persuasive. Applicants amended the claimed invention by adding the language "with no heat input at ambient temperature" and argues that the Asgharnejad et al patent uses heated air for its drying step which is different from amended Claim 1, which provides for "no heat input at ambient temperature". This argument is not persuasive since it is not clear how the ambient temperature was reached or how the ambient temperature is maintained without some type of temperature control. Is the drying step carried out at room temperature? If so, is the room temperature the same temperature outside the immediate location of the drying step? It is noted that the drying step in Example 1 of the instant specification is carried out for 16 hours. What type of system is Applicants using to maintain ambient temperature for this length of time? Does the ambient temperature used in the drying step comprise a wide range of temperature values?

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Applicants argue that Asgharnejad is only concerned with removing the ethanol/water granulating fluid, and contains no teaching that it is important or desirable to remove the ethanol component of the granulating fluid at a controlled rate. This argument is not persuasive since the Asgharnejad patent teaches carrying out a drying step that can take up to 24 hours, which suggests drying at a controlled rate.

Applicants argue that Asgharnejad exemplifies only a single step. This argument is not persuasive since the minimum amount of water used as a granulating fluid in combination with the polar organic solvent set forth in the instant claims is 15 parts water as described in the water to polar organic solvent ratio of 15:85. The percent composition of the ethanol and water as an azeotropic liquid in the CRC Handbook shows that the instant claims set forth an excess amount of water. By having an excess amount of water, steps (b) and (c) of the instant claims only set forth a normal drying procedure for removing azeotropic liquids containing ethanol and water wherein there is an excess amount of water. Once all the azeotropic liquid (ethanol/water combination) is removed, the excess amount of water in the process still remains in the drying vessel, which applicants removes in step (c), probably at a different temperature or pressure than what was used in step (b). The Asgharnejad et al patent also contains an excess amount of water along with the ethanol and water azeotrope combination, which would remain in the drying vessel after the initial removal of the ethanol/water azeotrope. See column 3, line 28 of the Asgharnejad et al patent wherein the combination of ethanol and water may preferably comprise as low as 5% ethanol, which is well within the range of having an excess amount of water with an azeotrope of ethanol and water. The excess water set forth in the granulating fluid of the instant claims causes the extra process step (step c) in the instant claims which would be an inherent feature of the process set forth in the Asgharnejad et al patent since the Asgharnejad et al patent also discloses excess water in the granulating fluid thereof.

Accordingly, for the above stated reasons, the rejection of Claims 1, 2, and 4-11 under 35 U.S.C. 102(e) as being anticipated by the Asgharnejad et al patent is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

6. Claims 1-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharnejad et al (US Patent No. 6,123,964) for the reasons set forth on pages 5-7 of the Office Action mailed July 15, 2003.
7. Applicant's arguments filed October 15, 2003 have been fully considered but they are not persuasive. The rejection of Claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over the Asgharnejad et al patent is maintained for the same reasons presented in the above rejection over the Asgharnejad et al patent under 35 U.S.C. 102(e).
8. Claim 3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharnejad et al (US Patent No. 6,123,964) as applied to Claims 1-13 above, and further in view of Flanner et al (US Patent No. 6,384,020) for the reasons set forth on pages 7-9 of the Office Action mailed July 15, 2003.
9. Applicant's arguments filed October 15, 2003 have been fully considered but they are not persuasive. Applicants argue an improper rejection of Claim 3 under 35 U.S.C. 102(e) over the Asgharnejad patent taken alone. The argument is not persuasive since Claim 3 was not rejected under 102(e) in the last Office Action mailed July 15, 2003. Applicant further argue that the 35 U.S.C. 103 rejection based on Flanner is overcome because Asgharnejad does not disclose the newly amended limitation of having "no heat input at ambient temperature" and Flanner et al does not cure this deficiency of the Asgharnejad patent. This argument is not persuasive for the reasons discussed above in the arguments presented in the rejection of the claims under 35 U.S.C. 102(e) over the Asgharnejad et al patent. Accordingly, the rejection of Claim 3 under 35 U.S.C. 103(a) as being obvious over the Asgharnejad et al patent in view of the Flanner et al patent is maintained for the reasons of record.
10. Claims 12 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharnejad et al (US Patent No. 6,123,964) as applied to Claims 1-13 above, and

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further in view of Erkoboni et al (US Patent No. 5,725,886) for the reasons set forth on pages 9 and 10 of the Office Action mailed July 15, 2003.

11. Applicant's arguments filed October 15, 2003 have been fully considered but they are not persuasive. Applicants argue an improper rejection of Claims 12 and 13 under 35 U.S.C. 102(e) over the Asgharnedjad taken alone. The argument is not persuasive since Claims 12 and 13 were not rejected under 102(e) in the last Office Action mailed July 15, 2003. Applicant further argues that the 35 U.S.C. 103 rejection based on Erkoboni et al patent is overcome because Asgharnedjad does not disclose the newly amended limitation of having "no heat input at ambient temperature" and Erkoboni et al does not cure this deficiency of the Asgharnejad patent. This argument is not persuasive for the reasons discussed above in the arguments presented in the rejection of the claims under 35 U.S.C. 102(e) over the Asgharnedjad et al patent. Accordingly, the rejection of Claims 12 and 13 under 35 U.S.C. 103(a) as being obvious over the Asgharnejad et al patent in view of the Erkoboni et al patent is maintained for the reasons of record.

12. Claims 14-16 and 18-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al (US Patent No. 6,149,943) for the reasons set forth on pages 10 and 11 of the Office Action mailed July 15, 2003.

13. Applicant's arguments filed October 15, 2003 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the average particle size of the microcrystalline cellulose disclosed in the McTeigue et al patent may be 220 microns wherein the mean particle size of the microcrystalline cellulose set forth in the instant claims are at least 250 microns. It is noted on page 7, 3rd full paragraph of the instant specification that the mean particle size of microcrystalline cellulose is preferably 200-1500 microns, more preferably 250-1000 microns. Hence, the instantly claimed microcrystalline cellulose having mean particle size of from about 250 to about 1500 microns is only a preferred range. The mean particle size for the microcrystalline cellulose of 200 to 220 microns set forth in the McTeigue et al patent falls within the preferred range that is taught in the instant

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specification. The disclosure of the instant specification does not support the criticality of the claimed mean particle size of the microcrystalline cellulose over the mean particle size of the microcrystalline cellulose set forth in the McTeigue et al patent. The fact that the percentages of the chemical components of a chemical compound fall within the general proportions of the references does not preclude patentability where the disclosure of the specification is persuasive of the criticality of the claimed proportions. *Ex parte Selby* (POBA 1966) 153 USPQ 476; *In re Waymouth et al.* (CCPA 1974) 499 F2d 1273, 182 USPQ 290. *In re Russell* (CCPA 1971) 439 F2d 1228, 169 USPQ 426. Contra, where the claimed range overlaps that of the prior art and no unexpected properties are shown or a teaching away from the claimed range. *In re Malagari* (CCPA 1974) 499 F2d 1297, 182 USPQ 549. Accordingly, the rejection Claims 14-16 and 18-26 under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al is maintained for the reasons of record.

14. Claim 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al (US Patent No. 6,149,943) as applied to Claims 14-16 and 18-26 above, and further in view of Kumar (US Patent No. 6,117,451).

15. Applicant's arguments filed October 15, 2003 have been fully considered but they are not persuasive. The rejection of Claim 17 as being unpatentable over the McTeigue et al patent as applied to Claims 14-16 and 18-26 above, and further in view of the Kumar patent is maintained for the same reason presented in the above arguments under 35 U.S.C. 103 against the McTeigue et al patent alone.

Summary

16. All the pending claims are rejected.

ACTION MADE FINAL

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information


18. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


E.White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600